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(54) Title: DEVICES, SYSTEMS, AND METHODS FOR SUPPLEMENTING, REPAIRING, OR REPLACING A NATIVE HEART VALVE LEAFLET

(57) Abstract: Devices, systems and methods supplement, repair, or replace a native heart valve. The devices, systems, and methods employ an implant that, in use, extends adjacent a valve annulus. The implant includes a mobile neoleaflet element that occupies the space of at least a portion of one native valve leaflet. The implant mimics the one-way valve function of a native leaflet, to resist or prevent retrograde flow. The implant restores normal coaptation of the leaflets to resist retrograde flow, thereby resisting eversion and/or prolapse, which, in turn, reduces regurgitation.

DEVICES, SYSTEMS, AND METHODS FOR
SUPPLEMENTING, REPAIRING, OR REPLACING
A NATIVE HEART VALVE LEAFLET

Related Applications

5 This application claims the benefit of co-pending United States Patent Application Serial No. 09/666,617, filed September 20, 2000 and entitled "Heart Valve Annulus Device and Methods of Using Same," which is incorporated herein by reference. This application also

10 claims the benefit of Patent Cooperation Treaty Application Serial No. PCT/US 02/31376, filed October 1, 2002 and entitled "Systems and Devices for Heart Valve Treatments," which claimed the benefit of United States Provisional Patent Application Serial No. 60/326,590, filed October 1, 2001, which are incorporated herein by reference. This application also claims the benefit of United States Provisional Application Serial No. 60/429,444, filed November 26, 2002, and entitled "Heart Valve Remodeling Devices;" United States Provisional

15 Patent Application Serial No. 60/429,709, filed November 26, 2002, and entitled "Neo-Leaflet Medical Devices;" and United States Provisional Patent Application Serial No. 60/429,462, filed November 26, 2002, and entitled "Heart Valve Leaflet Retaining Devices," which are each

20 incorporated herein by reference.

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Field of the Invention

The invention is directed to devices, systems, and methods for improving the function of a heart valve, e.g., in the treatment of mitral valve regurgitation.

5 Background of the Invention

I. The Anatomy of a Healthy Heart

The heart (see Fig. 1) is slightly larger than a clenched fist. It is a double (left and right side), self-adjusting muscular pump, the parts of which work in unison to propel blood to all parts of the body. The right side of the heart receives poorly oxygenated ("venous") blood from the body from the superior vena cava and inferior vena cava and pumps it through the pulmonary artery to the lungs for oxygenation. The left side receives well-oxygenation ("arterial") blood from the lungs through the pulmonary veins and pumps it into the aorta for distribution to the body.

The heart has four chambers, two on each side -- the right and left atria, and the right and left ventricles. The atria are the blood-receiving chambers, which pump blood into the ventricles. A wall composed of membranous and muscular parts, called the interatrial septum, separates the right and left atria. The ventricles are the blood-discharging chambers. A wall composed of membranous and muscular parts, called the interventricular septum, separates the right and left ventricles.

The synchronous pumping actions of the left and right sides of the heart constitute the cardiac cycle. The cycle begins with a period of ventricular relaxation, called ventricular diastole. The cycle ends with a period of ventricular contraction, called ventricular systole.

The heart has four valves (see Figs. 2 and 3) that ensure that blood does not flow in the wrong

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direction during the cardiac cycle; that is, to ensure that the blood does not back flow from the ventricles into the corresponding atria, or back flow from the arteries into the corresponding ventricles. The valve 5 between the left atrium and the left ventricle is the mitral valve. The valve between the right atrium and the right ventricle is the tricuspid valve. The pulmonary valve is at the opening of the pulmonary artery. The aortic valve is at the opening of the aorta.

10 At the beginning of ventricular diastole (i.e., ventricular filling) (see Fig. 2), the aortic and pulmonary valves are closed to prevent back flow from the arteries into the ventricles. Shortly thereafter, the tricuspid and mitral valves open (as Fig. 2 shows), to 15 allow flow from the atria into the corresponding ventricles. Shortly after ventricular systole (i.e., ventricular emptying) begins, the tricuspid and mitral valves close (see Fig. 3) -- to prevent back flow from the ventricles into the corresponding atria -- and the 20 aortic and pulmonary valves open -- to permit discharge of blood into the arteries from the corresponding ventricles.

The opening and closing of heart valves occur primarily as a result of pressure differences. For 25 example, the opening and closing of the mitral valve occurs as a result of the pressure differences between the left atrium and the left ventricle. During ventricular diastole, when ventricles are relaxed, the venous return of blood from the pulmonary veins into the 30 left atrium causes the pressure in the atrium to exceed that in the ventricle. As a result, the mitral valve opens, allowing blood to enter the ventricle. As the ventricle contracts during ventricular systole, the intraventricular pressure rises above the pressure in the 35 atrium and pushes the mitral valve shut.

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Fig. 4 shows a posterior oblique cutaway view of a healthy human heart 100. Two of the four heart chambers are shown, the left atrium 170, and the left ventricle 140 (not shown are the right atrium and right ventricle). The left atrium 170 fills with blood from the pulmonary veins. The blood then passes through the mitral valve (also known as the bicuspid valve, and more generally known as an atrioventricular valve) during ventricular diastole and into the left ventricle 140. During ventricular systole, the blood is then ejected out of the left ventricle 140 through the aortic valve 150 and into the aorta 160. At this time, the mitral valve should be shut so that blood is not regurgitated back into the left atrium.

The mitral valve consists of two leaflets, an anterior leaflet 110, and a posterior leaflet 115, attached to chordae tendineae 120 (or chords), which in turn are connected to papillary muscles 130 within the left atrium 140. Typically, the mitral valve has a D-shaped anterior leaflet 110 oriented toward the aortic valve, with a crescent shaped posterior leaflet 115. The leaflets intersect with the atrium 170 at the mitral annulus 190.

In a healthy heart, these muscles and their chords support the mitral and tricuspid valves, allowing the leaflets to resist the high pressure developed during contractions (pumping) of the left and right ventricles. In a healthy heart, the chords become taut, preventing the leaflets from being forced into the left or right atria and everted. Prolapse is a term used to describe the condition wherein the coaptation edges of each leaflet initially may coapt and close, but then the leaflets rise higher and the edges separate and the valve leaks. This is normally prevented by contraction of the papillary muscles and the normal length of the chords.

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Contraction of the papillary muscles is simultaneous with the contraction of the ventricle and serves to keep healthy valve leaflets tightly shut at peak contraction pressures exerted by the ventricle.

5 **II. Characteristics and Causes of Mitral Valve Dysfunction**

Valve malfunction can result from the chords becoming stretched, and in some cases tearing. When a chord tears, the result is a flailed leaflet. Also, a 10 normally structured valve may not function properly because of an enlargement of the valve annulus pulling the leaflets apart. This condition is referred to as a dilation of the annulus and generally results from heart muscle failure. In addition, the valve may be defective 15 at birth or because of an acquired disease, usually infectious or inflammatory.

Fig. 5 shows a cutaway view of a human heart 200 with a prolapsed mitral valve. The prolapsed valve does not form a tight seal during ventricular systole, 20 and thus allows blood to be regurgitated back into the left atrium during ventricular contraction. The anterior 220 and posterior 225 leaflets are shown rising higher than normal (i.e., prolapsing) into the left atrium. The arrows indicate the direction of regurgitant flow. Among 25 other causes, regurgitation can result from redundant valve leaflet tissue or from stretched chords 210 that are too long to prevent the leaflets from being blown into the atrium. As a result, the leaflets do not form a tight seal, and blood is regurgitated into the atrium.

30 Fig. 6 shows a cutaway view of a human heart 300 with a flailing mitral valve 320. The flailing valve also does not form a tight seal during ventricular systole. Blood thus regurgitates back into the left atrium during ventricular contraction, as indicated by 35 the arrows. Among other causes, regurgitation can also

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result from torn chords 310. As an example, Fig. 7 shows a cutaway view of a human heart where the anterior leaflet 910 has torn chords 920. As a result, valve flailing and blood regurgitation occur during ventricular systole.

As a result of regurgitation, "extra" blood back flows into the left atrium. During subsequent ventricular diastole (when the heart relaxes), this "extra" blood returns to the left ventricle, creating a volume overload, i.e., too much blood in the left ventricle. During subsequent ventricular systole (when the heart contracts), there is more blood in the ventricle than expected. This means that: (1) the heart must pump harder to move the extra blood; (2) too little blood may move from the heart to the rest of the body; and (3) over time, the left ventricle may begin to stretch and enlarge to accommodate the larger volume of blood, and the left ventricle may become weaker.

Although mild cases of mitral valve regurgitation result in few problems, more severe and chronic cases eventually weaken the heart and can result in heart failure. Mitral valve regurgitation can be an acute or chronic condition. It is sometimes called mitral insufficiency.

25 III. Prior Treatment Modalities

In the treatment of mitral valve regurgitation, diuretics and/or vasodilators can be used to help reduce the amount of blood flowing back into the left atrium. An intra-aortic balloon counterpulsation device is used if the condition is not stabilized with medications. For chronic or acute mitral valve regurgitation, surgery to repair or replace the mitral valve is often necessary.

To date, invasive, open heart surgical approaches have been used to repair or replace the mitral

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valve with either a mechanical valve or biological tissue (bioprosthetic) taken from pigs, cows, or horses.

The need remains for simple, cost-effective, and less invasive devices, systems, and methods for 5 treating dysfunction of a heart valve, e.g., in the treatment of mitral valve regurgitation.

Summary of the Invention

The invention provides devices, systems and methods that supplement, repair, or replace a native 10 heart valve leaflet. The devices, systems, and methods include an implant that, in use, rests adjacent a valve annulus. The implant defines a pseudo-annulus. The implant includes a neoleaflet element that occupies the space of at least a portion of one native valve leaflet. 15 The implant allows the native leaflets to coexist with the implant, or if desired or indicated, one or more native leaflets can be removed and replaced by the implant. The neoleaflet element of the implant is shaped and compressed to mimic the one-way valve function of a 20 native leaflet. The implant includes spaced-apart struts that are sized and configured to contact tissue near or within the heart valve annulus to brace the implant against migration within the annulus during the one-way valve function.

25 Other features and advantages of the invention shall be apparent based upon the accompanying description, drawings, and claims.

Description of the Drawings

Fig. 1 is a perspective, anterior anatomic 30 view of the interior of a healthy heart.

Fig. 2 is a superior anatomic view of the interior of a healthy heart, with the atria removed, showing the condition of the heart valves during ventricular diastole.

35 Fig. 3 is a superior anatomic view of the

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interior of a healthy heart, with the atria removed, showing the condition of the heart valves during ventricular systole.

Fig. 4 is a posterior oblique cutaway view of 5 a portion of a human heart, showing a healthy mitral valve during ventricular systole, with the leaflets properly coapting.

Fig. 5 is a posterior oblique cutaway view of 10 a portion of a human heart, showing a dysfunctional prolapsing mitral valve during ventricular systole, with the leaflets not properly coapting, causing regurgitation.

Fig. 6 is a posterior oblique cutaway view of 15 a portion of a human heart, showing a dysfunctional mitral valve during ventricular systole, with the leaflets flailing, causing regurgitation.

Fig. 7 is a posterior oblique cutaway view of 20 a portion of a human heart, showing a dysfunctional mitral valve during ventricular systole, caused by torn chords, that leads to regurgitation.

Fig. 8 is a perspective view of an implant 25 that supplements, repairs, or replaces a native heart valve leaflet, the implant being sized and configured to extend about a heart valve annulus and including a neoleaflet element that occupies the space of at least one native valve leaflet.

Fig. 9A is a perspective, anatomic view of the 30 implant shown in Fig. 8, with the neoleaflet element installed over an anterior leaflet of a mitral valve to restore normal function.

Fig. 9B is a perspective, anatomic view of the 35 implant of the type shown in Fig. 8, with the neoleaflet element installed over a posterior leaflet of a mitral valve to restore normal function to the native valve leaflet.

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Fig. 10 is a perspective view of another illustrative embodiment of an implant that supplements, repairs, or replaces a native heart valve leaflet, the implant being shown installed on a mitral valve annulus 5 and having a neoleaflet element that occupies the space of at least one native valve leaflet, the implant also including a framework that rises above the neoleaflet element in the atrium to help fix and stabilize the implant.

10 Fig. 11 is a perspective view of another illustrative embodiment of an implant that supplements, repairs, or replaces a native heart valve leaflet, the implant being sized and configured to extend about a heart valve annulus and including two neoleaflet 15 elements that occupy the space of two native valve leaflets.

Fig. 12 is a perspective view of the implant shown in Fig. 11, with the two neoleaflet elements in a valve opened condition, as would exist during ventricular 20 diastole.

Fig. 13 is a perspective view of another illustrative embodiment of an implant that supplements, repairs, or replaces a native heart valve leaflet, the implant being sized and configured to extend about a heart valve annulus and including a neoleaflet element 25 formed by a membrane.

Fig. 14 is a perspective view of another illustrative embodiment of an implant that supplements, repairs, or replaces a native heart valve leaflet, the 30 implant being sized and configured to extend about a heart valve annulus and including a neoleaflet element formed by a membrane, the implant also including a framework that rises above the neoleaflet element in the atrium to help fix and stabilize the implant.

35 Fig. 15 is a perspective view of another

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illustrative embodiment of an implant that supplements, repairs, or replaces a native heart valve leaflet, the implant being sized and configured to extend about a heart valve annulus and including two neoleaflet elements 5 to form a duckbill valve, the valve being shown in an opened condition as would exist during ventricular diastole.

Fig. 16 is a perspective view of the implant shown in Fig. 15, the duckbill valve being shown in a 10 closed condition as would exist during ventricular systole.

Figs. 17 and 18 are side views of the implant shown, respectively, in Figs. 15 and 16, with the duckbill valve, respectively, in an opened and a closed 15 condition.

Fig. 19 is a perspective view of another illustrative embodiment of an implant that supplements, repairs, or replaces a native heart valve leaflet, the implant being sized and configured to extend about a heart valve annulus and including two neoleaflet elements 20 formed by a duckbill valve, the valve being shown in an opened condition as would exist during ventricular diastole, the implant also including a framework that rises above the neoleaflet elements in the atrium to help 25 fix and stabilize the implant.

Fig. 20 is a perspective view of the implant shown in Fig. 19, the duckbill valve being shown in a closed condition as would exist during ventricular systole.

30 Figs. 21A to 21C diagrammatically show a method of gaining intravascular access to the left atrium for the purpose of deploying a delivery catheter to place an implant in a valve annulus to supplement, repair, or replace a native heart valve leaflet

35 Detailed Description

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Although the disclosure hereof is detailed and exact to enable those skilled in the art to practice the invention, the physical embodiments herein disclosed merely exemplify the invention, which may be embodied in 5 other specific structure. While the preferred embodiment has been described, the details may be changed without departing from the invention, which is defined by the claims.

Figs. 8 and 9 show an implant 400 sized and 10 configured to supplement, repair, or replace a dysfunctional native heart valve leaflet or leaflets. In use (see, in particular, Fig. 9), the implant 400 defines a pseudo-annulus that rests adjacent the native valve annulus and includes a neoleaflet element that occupies 15 the space of at least a portion of one native valve leaflet. The implant 400 allows the native leaflets to coexist with the implant 400. If desired or indicated, one or more native leaflets can be removed and replaced by the implant 400.

20 In its most basic form, the implant 400 is made -- e.g., by machining, bending, shaping, joining, molding, or extrusion -- from a biocompatible metallic or polymer material, or a metallic or polymer material that is suitably coated, impregnated, or otherwise treated 25 with a material to impart biocompatibility, or a combination of such materials. The material is also desirably radio-opaque to facilitate fluoroscopic visualization.

As Fig. 8 shows, the implant 400 includes a 30 base or scaffold 420 that, in the illustrated embodiment, is sized and configured to rest adjacent the mitral annulus. At least a portion of the base 420 forms an annular body that approximates the shape of the native annulus. For this reason, the base 420 will also be 35 referred to as a "pseudo-annulus."

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The base 420 supports a bridge 430 that extends into the valve. The bridge 430 is sized and configured (see Fig. 9A) to overlay the space of at least a portion of one native valve leaflet. In Fig. 9A, the 5 bridge 430 overlays an anterior leaflet. However, as Fig. 9B shows, the bridge 430 could be oriented to overlay a posterior leaflet. As will be described later (see Fig. 11), two bridges can be formed to overlay both leaflets.

As Fig. 8 shows, the implant 400 includes a 10 material 410 that covers or spans the bridge 430. The spanning material 410 may be attached to the implant 400 with one or more attachment means 440. For example, the spanning materials 410 may be sewn, glued, or welded to the implant 400, or it may be attached to itself when 15 wrapped around the implant 400. The spanning material 410 may be made from a synthetic material (for example, thin Nitinol, polyester fabric, polytetrafluoroethylene or PTFE, silicone, or polyurethane) or a biological material (for example, human or animal pericardium).

20 Together, the bridge 430 and the spanning material 410 comprise a neoleaflet element 470 coupled to the base 420. The neoleaflet element 470 may be rigid, semi-rigid, or flexible. The neoleaflet element 470 is coupled to the base 420 in a manner that exerts a 25 mechanical, one-way force to provide a valve function that responds to differential pressure conditions across the neoleaflet element. In response to one prescribed differential pressure condition, the neoleaflet element 470 will deflect and, with a native leaflet, assume a 30 valve opened condition. In response to another prescribed pressure condition, the neoleaflet element 470 will resist deflection and, by coaptation with a native leaflet (or a companion neoleaflet element) at, above, or below the annulus plane, maintain a valve closed 35 condition.

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In the context of the illustrated embodiment (when installed in a mitral valve annulus), the neoleaflet element resists being moved in the cranial (superior) direction (into the atrium), when the pressure 5 in the ventricle exceeds the pressure in the atrium -- as it would during ventricular systole. The neoleaflet element 470 may move, however, in the caudal (inferior) direction (into the ventricle), when the pressure in the ventricle is less than the pressure in the atrium -- as 10 it would during ventricular diastole. The neoleaflet element 470 thereby mimics the one-way valve function of a native leaflet, to prevent retrograde flow.

The implant 400 is sized and shaped so that, in use adjacent the valve annulus of the mitral valve, it 15 keeps the native valve leaflet closed during ventricular systole (as shown in Figs. 9A and 9B), to prevent flailing and/or prolapse of the native valve leaflet it overlays during ventricular systole. The implant 400 thus restores to the heart valve leaflet or leaflets a normal 20 resistance to the high pressure developed during ventricular contractions, resisting valve leaflet eversion and/or prolapse and the resulting back flow of blood from the ventricle into the atrium during ventricular systole. The pressure difference serves to 25 keep valve leaflets tightly shut during ventricular systole. The implant 400, however, does not interfere with opening of the native valve leaflet or leaflets during ventricular diastole (see, e.g., Fig. 12). The implant 400 allows the leaflet or leaflets to open during 30 ventricular diastole, so that blood flow occurs from the atrium into the ventricle. The implant 400 thereby restores normal one-way function to the valve, to prevent retrograde flow.

The functional characteristics of the implant 35 400 just described can be imparted to the neoleaflet

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element 470 in various ways. For example, hinges and springs (mechanical or plastic) can be used to couple the bridge to the base. Desirably, the implant 400 is made from materials that provide it with spring-like characteristics.

As shown in Fig. 8, in the illustrated embodiment, the base 420 and bridge 430 are shaped from a length of wire-formed material. The shape and material properties of the implant determine its physical spring-like characteristics as well as its ability to open in one direction only. The spring-like characteristics of the implant 400 allow it to respond dynamically to changing differential pressure conditions within the heart.

More particularly, in the illustrated mitral valve embodiment, when greater pressure exists superior to the bridge 430 than inferior to the bridge (i.e., during ventricular diastole), the shape and material properties of the bridge 430 accommodate its deflection into the ventricle -- i.e., an opened valve condition (as Fig. 12 shows in another illustrative embodiment). When greater pressure exists inferior to the bridge 430 than superior to the bridge (i.e., during ventricular systole), the shape and material properties of the bridge 430 enable it to resist superior movement of the leaflet into the atrium, and otherwise resist eversion and/or prolapse of the valve leaflet into the atrium (as Figs. 9A and 9B also show).

The implant 400 may be delivered percutaneously, thoracoscopically through the chest, or using open heart surgical techniques. If delivered percutaneously, the implant 400 may be made from a superelastic material (for example superelastic Nitinol alloy) enabling it to be folded and collapsed such that it can be delivered in a catheter, and will subsequently

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self-expand into the desired shape and tension when released from the catheter.

For example, percutaneous vascular access can be achieved by conventional methods into the femoral or 5 jugular vein. As Fig. 21A shows, under image guidance (e.g., fluoroscopic, ultrasonic, magnetic resonance, computed tomography, or combinations thereof), a catheter 52 is steered through the vasculature into the right atrium. A needle cannula 54 carried on the distal end of 10 the catheter is deployed to pierce the septum between the right and left atrium. As Fig. 21B shows, a guide wire 56 is advanced trans-septally through the needle catheter 52 into the left atrium. The first catheter 52 is withdrawn, and (as Fig. 21C shows) under image guidance, 15 an implant delivery catheter 58 is advanced over the guide wire 56 into the left atrium into proximity with the mitral valve. Alternatively, the implant delivery catheter 58 can be deployed trans-septally by means of surgical access through the right atrium.

20 The distal end of the catheter 58 encloses an implant 400, like that shown in Fig. 8, which is constrained in a collapsed condition. A flexible push rod in the catheter 58 can be used to expel the implant 400 from the catheter 58. Free of the catheter, the 25 implant 400 will self-expand to its preordained configuration, e.g., like that shown in Figs. 9A or 9B.

The implant 400 may be fixed to the annulus in various ways. For example, the implant 400 may be secured to the annulus with sutures or other attachment 30 means (i.e. barbs, hooks, staples, etc.) Also, the implant 400 may be secured with struts or tabs 450 (see Figs. 8 and 9A), that extend from the base 420 above or below the plane of the annulus. The struts 450 are preferably configured with narrow connecting members that 35 extend through the valve orifice so that they will not

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interfere with the opening and closing of the valve.

In this arrangement, the struts 450 are desirably sized and configured to contact tissue near or within the heart valve annulus to brace the base 420 against migration within the annulus during the one-way valve function of the neoleaflet element. In this arrangement, it is also desirable that the base 420 be "elastic," i.e., the material of the base 420 is selected to possess a desired spring constant. This means that the base 420 is sized and configured to possess a normal, unloaded, shape or condition (shown in Fig. 8), in which the base 420 is not in net compression, and the struts 450 are spaced apart farther than the longest cross-annulus distance between the tissue that the struts 450 are intended to contact. In the illustrated embodiment, the base 420 is shown resting along the major (i.e., longest) axis of the valve annulus, with the struts 450 contacting tissue at or near the leaflet commissures. However, other orientations are possible. The struts 450 need not rest at or near the leaflet commissures, but may be significantly removed from the commissures, so as to gain padding from the leaflets. The spring constant imparts to the base 420 the ability to be elastically compressed out of its normal, unloaded condition, in response to external compression forces applied at the struts 450. The base 420 is sized and configured to assume an elastically loaded, in net compression condition, during which the struts 450 are spaced apart a sufficiently shorter distance to rest in engagement with tissue at or near the leaflet commissures (or wherever tissue contact with the struts 450 is intended to occur) (see Figs. 9A or 9B). When in its elastically loaded, net compressed condition (see Figs. 9A and 9B), the base 450 can exert forces to the tissues through the struts 450. These forces hold the base 420 against migration within

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the annulus. Furthermore, when the struts 450 are positioned at or near the commissures, they tend to outwardly displace tissue and separate tissue along the major axis of the annulus, which also typically stretches 5 the leaflet commissures, shortens the minor axis, and/or reshapes surrounding anatomic structures. The base 450 can also thereby reshape the valve annulus toward a shape more conducive to leaflet coaptation. It should be appreciated that, in order to be therapeutic, the implant 10 may only need to reshape the annulus during a portion of the heart cycle, such as during ventricular systolic contraction. For example, the implant may be sized to produce small or negligible outward displacement of tissue during ventricular diastole when the tissue is 15 relaxed, but restrict the inward movement of tissue during ventricular systolic contraction.

As the preceding disclosure demonstrates, different forms of heart valve treatment can be performed using a single implant.

20 Implants having one or more of the technical features just described, to thereby function *in situ* as a neo-leaflet, may be sized and configured in various ways. Various illustrative embodiments will now be described.

25 In Fig. 10, an implant 600 (like implant 400) includes a base 620 that defines a pseudo-annulus, with a bridge 630 carrying a spanning material 640 together comprising a neoleaflet element 650 appended to the base 620 within the pseudo-annulus. The neoleaflet element 650 overlays an anterior native leaflet with the same purpose 30 and function described for the implant 400. Alternatively, the neoleaflet element 650 could overlay a posterior native leaflet, as Fig. 9B shows. The implant 600 also includes struts 670, which desirably contact and exert force against tissue near or within the annulus (in 35 the manner previously described) to brace the base 420

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against migration within the annulus.

In addition, the implant 600 includes an orientation and stabilization framework 610 that may extend from the annulus to the atrial dome. In Fig. 10, 5 the framework 610 rises from the base 620 with two substantially parallel arched wires, which connect to form a semicircular hoop above the base 620. The framework 610 helps to accurately position the implant 600 within the atrium, and also helps to secure the 10 implant 600 within the atrium.

Preferably the framework 610 does not interfere with atrial contractions, but instead is compliant enough to contract with the atrium. As such, 15 the implant 600 may have nonuniform flexibility to improve its function within the heart.

Figs. 11 and 12 show another illustrative embodiment of an implant 700. In Figs. 11 and 12, the implant 700 contains two neo-leaflet elements. The implant 700 includes an anterior bridge 730 spanned by an 20 anterior bridge material 710, and a posterior bridge 735 spanned by a posterior bridge material 720. The bridges and materials together comprise anterior and posterior neoleaflet elements 780A and 780P. The implant 700 also includes an orientation and stabilization framework 770, 25 shown having a configuration different than the framework 610 in Fig. 9, but having the same function and serving the same purpose as previously described for the framework 610.

In Figs. 11 and 12, the base 760 includes 30 structures like the anchoring clips 740 that, in use, protrude above the plane formed by the annulus of the valve. Additionally, the implant 700 may be secured with struts 750 that extend from the base 760 on narrow connecting members and below the plane of the annulus 35 into the ventricular chamber. The anchoring clips 740 and

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struts 750 desirably contact and exert force against tissue near or within the annulus (in the manner previously described) to brace the base 760 against migration within the annulus. Fig. 11 shows the dual neo-
5 leaflets 780A and 780B (i.e., the covered anterior and posterior bridges 730 and 735) in a closed valve position. Fig. 12 shows the dual neo-leaflets 780A and 780B in an open valve position.

Fig. 13 shows another illustrative embodiment 10 of an implant 1000 having a full sewing ring 1030 with a membrane 1010 that serves as a neo-leaflet. The device 1000 has an opening 1020 though the sewing ring 1030 opposite the membrane 1010 for blood flow. Alternatively, this embodiment could have two neo-leaflets. This 15 embodiment could be surgically attached to the valve annulus and/or combined with a framework for anchoring the device within the atrium using catheter based intraluminal techniques. Additionally, the device may be secured with struts 1040 that extend from the base on narrow connecting members and below the plane of the 20 annulus into the ventricular chamber. The struts 1040, which desirably contact and exert force against tissue near or within the annulus (in the manner previously described) to brace the base 420 against migration within 25 the annulus.

As can be seen, a given implant may carry various structures or mechanisms to enhance the anchorage and stabilization of the implant in the heart valve annulus. The mechanisms may be located below the plane of 30 the annulus, to engage infra-annular heart tissue adjoining the annulus in the ventricle, and/or be located at or above the plane of the annulus, to engage tissue on the annulus or in the atrium. These mechanisms increase the surface area of contact between the implant and 35 tissue. A given implant can also include tissue in-

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growth surfaces, to provide an environment that encourages the in-growth of neighboring tissue on the implant. Once in-growth occurs, the implant becomes resistant to migration or dislodgment from the annulus.

5 Conventional in-growth materials such as polyester fabric can be used.

Fig. 14 shows another illustrative embodiment of an implant 1100 having a framework 1120 and struts or tabs 1110. This implant 1100 includes a membrane 1130, 10 that serves as a neo-leaflet, attached to the base 1140 of the device with an attachment means 1150.

Fig. 15 shows another illustrative embodiment of an implant 1200. In this embodiment, the implant 1200 includes a base 1220 that defines a pseudo-annulus and 15 that, in use, is rests adjacent all or a portion of a native valve annulus. The base 1240 supports a duckbill valve 1210, which forms a neoleaflet element. Peripherally supported on the base 1240, the duckbill valve 1210 rests in the pseudo-annulus. Struts 1230 20 (which also carry additional tab structures to increase the surface area of tissue contact) help brace the base 1240 to tissue near or within the heart valve annulus.

In this embodiment, the duckbill valve 1210 replaces the native anterior and posterior leaflets. The 25 duckbill valve 1210 serves as dual neo-leaflets, which mutually open and close in response to changes in pressure, replacing the function of the native leaflets. Fig. 15 shows the duckbill valve 1210 in the open valve position. In Fig. 15, the arrow shows the direction of 30 blood flow through the opened valve. Fig. 16 shows the duckbill valve in the closed valve position. When closed, the duckbill valve 1210 resists eversion and regurgitation.

When the implant 1200 is used to replace a 35 mitral valve (see Figs. 17 and 18), the duckbill valve

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1210 extends from the plane of the valve annulus and into the ventricle. The duckbill valve 1210 is shown to have a more rigid or thick composition emerging from the base member, and gradually becoming less rigid or thick away 5 from the base member. This variation in mechanical properties ensures a valve that responds dynamically to pressure changes, but that is also rigid enough to not become everted. Fig. 17 shows the valve 1210 in an opened valve condition. In Fig. 17, the arrow shows the 10 direction of blood flow through the opened valve. Fig. 18 shows the duckbill valve in the closed valve position, without eversion and regurgitation.

Figs. 19 and 20 show another illustrative embodiment of an implant 1600 of the type shown in Figs. 15 and 16. Like the implant 1200, the implant 1600 includes base 1620 defining a pseudo-annulus to which a duckbill valve 1630 is appended, which serves as a neoleaflet element to replace the native anterior and posterior leaflets and serves as dual neo-leaflets. Fig. 20 19 shows the duckbill valve 1630 in the open valve position, allowing forward flow of blood through the opened valve. Fig. 20 shows the duckbill valve 1630 in the closed valve position, resisting eversion and regurgitation.

25 In Figs. 19 and 20, the implant 1600 includes an orientation and stabilization framework 1610. The framework 1610 rises from the base 1620 as two arches extending from opposite sides of the base 1620. The dual arch framework 1610 possesses compliance to contract with 30 the atrium. As before explained, the framework 1610 helps to accurately position the implant 1600 within the atrium, and also helps to secure the implant 600 within the atrium. The implant 1600 also includes struts 1640, which desirably contact and exert force against tissue 35 near or within the annulus (in the manner previously

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described) to brace the base 1620 against migration within the annulus.

While the new devices and methods have been more specifically described in the context of the 5 treatment of a mitral heart valve, it should be understood that other heart valve types can be treated in the same or equivalent fashion. By way of example, and not by limitation, the present systems and methods could be used to prevent or resist retrograde flow in any heart 10 valve annulus, including the tricuspid valve, the pulmonary valve, or the aortic valve. In addition, other embodiments and uses of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed 15 herein. The specification and examples should be considered exemplary and merely descriptive of key technical features and principles, and are not meant to be limiting. The true scope and spirit of the invention are defined by the following claims. As will be easily 20 understood by those of ordinary skill in the art, variations and modifications of each of the disclosed embodiments can be easily made within the scope of this invention as defined by the following claims.

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What is claimed is:

1. An implant that supplements, repairs, or replaces a native heart valve leaflet or leaflets comprising
 - 5 a scaffold sized and configured to rest adjacent all or a portion of a native heart valve annulus, at least a portion of the scaffold defining a pseudo-annulus,
 - 10 a neoleaflet element coupled to the scaffold within pseudo-annulus and being sized and shaped to occupy the space of at least a portion of one native heart valve leaflet to provide a one-way valve function that, in response to a first pressure condition, assumes a valve opened condition within the pseudo-annulus and,
 - 15 in response to a second pressure condition, assumes a valve closed condition within the pseudo-annulus, and
 - 20 spaced-apart struts appended to the scaffold and being sized and configured to contact tissue near or within the heart valve annulus to brace the scaffold against migration within the annulus during the one-way valve function.
 2. An implant according to claim 1 wherein the scaffold comprises a wire-form structure.
 - 25 3. An implant according to claim 1 wherein at least one of the struts comprises a wire-form structure.
 - 30 4. An implant according to claim 1 wherein the scaffold and the struts each comprises a wire-form structure.
 5. An implant according to claim 1 wherein the neoleaflet element includes a bridge appended to the scaffold.
 - 35 6. An implant according to claim 5 wherein the neoleaflet element includes a

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material covering the bridge.

7. An implant according to claim 5
wherein the bridge is a wire-form structure.

8. An implant according to claim 1
5 wherein the neoleaflet element includes a
duckbill valve within the psuedo-annulus.

9. An implant according to claim 1
wherein the neoleaflet element includes a
membrane within the pseudo-annulus.

10. An implant according to claim 1
wherein the neoleaflet element is sized and
configured to coapt with a native leaflet when in the
valve closed condition.

11. An implant according to claim 1
15 wherein the scaffold, neoleaflet element, and
the struts are collapsible for placement within a
catheter.

12. An implant according to claim 1
wherein at least one of the struts carries a
20 structure sized and configured to increase a surface area
of contact with tissue at, above, or below the annulus.

13. An implant according to claim 1
further including at least one structure
appended to the scaffold and being sized and configured
25 to contact tissue at, above, or below the heart valve
annulus to stabilize the scaffold.

14. An implant according to claim 1
wherein the scaffold, neoleaflet element, and
struts include materials and shapes to provide a spring-
30 like bias for compliance with anatomy near or within the
heart valve annulus.

15. An implant according to claim 1
wherein the struts apply tension to tissue.

16. An implant according to claim 1
35 wherein the struts apply tension to tissue to

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reshape the heart valve annulus.

17. An implant according to claim 1

wherein the struts apply tension to separate tissue along an axis of the heart valve annulus.

5 18. An implant according to claim 1

further including a second heart valve treatment element appended to the scaffold to affect a heart valve function.

19. An implant according to claim 18

10. wherein the second heart valve treatment element includes means for reshaping the heart valve annulus for leaflet coaptation.

20. An implant according to claim 18

wherein the second heart valve treatment 15 element includes means for stretching leaflet commissures for leaflet coaptation.

21. A method for supplementing, repairing, or replacing a native heart valve leaflet or leaflets comprising the steps of

20. introducing an implant as defined in claim 1 into a heart, and

providing a one-way valve function that, in response to a first pressure condition, assumes a valve opened condition and, in response to second pressure 25 condition, assumes a valve closed condition by locating the scaffold as defined in claim 1 adjacent all or a portion of a native heart valve annulus to define a pseudo-annulus, with the neoleaflet element as defined in claim 1 occupying the space of at least a portion of one 30 native heart valve leaflet to provide the one-way valve function, and with the spaced-apart struts as defined in claim 1 contacting tissue near or within the heart valve annulus to brace the scaffold against migration within the annulus during the one-way valve function.

35 22. A method according to claim 21

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wherein the introducing step comprises using an open heart surgical procedure.

23. A method according to claim 21 wherein the introducing step comprises using a 5 surgical procedure in which the implant is carried within a catheter.

24. A method according to claim 21 wherein the introducing step comprises using an intravascular surgical procedure.

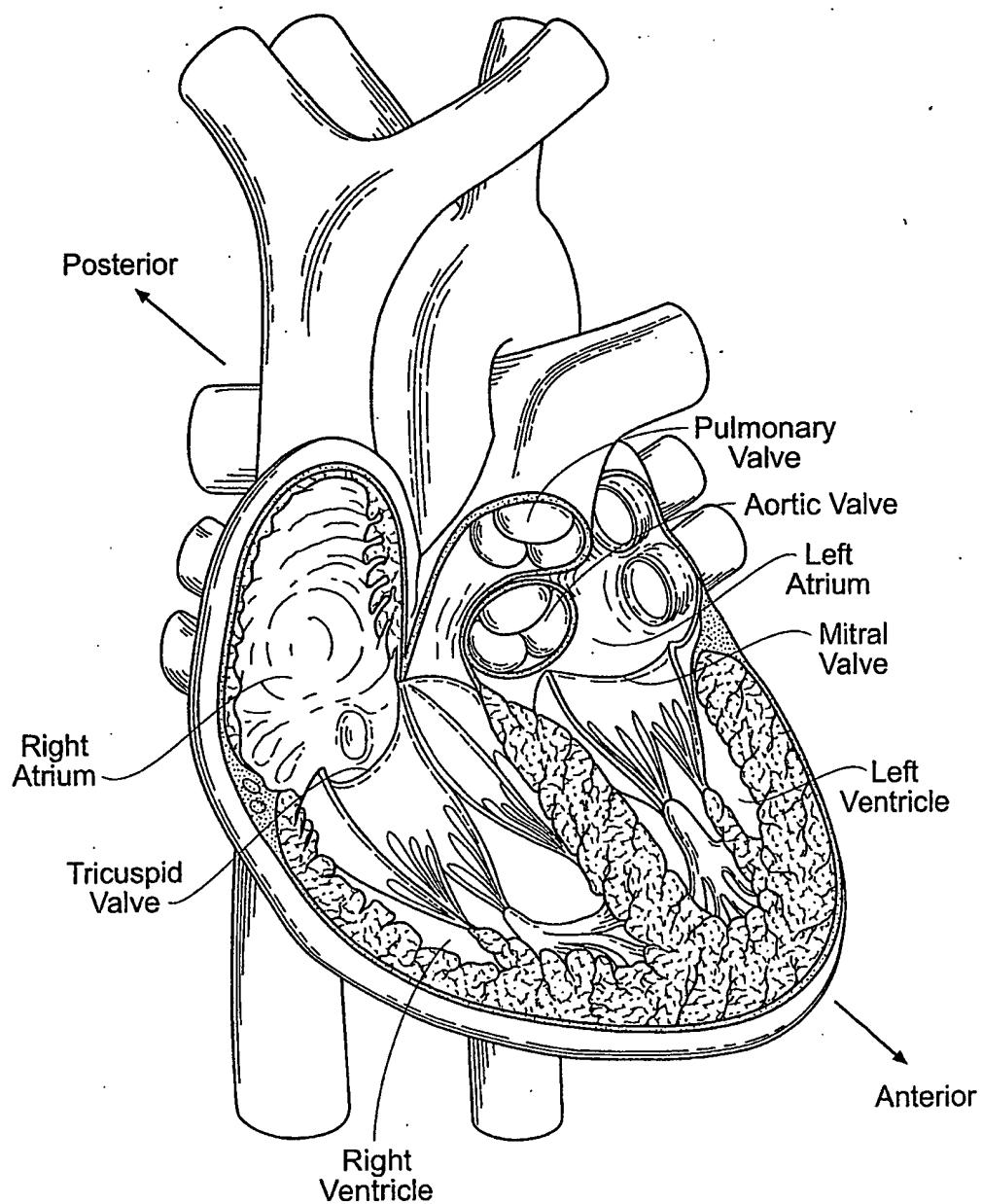
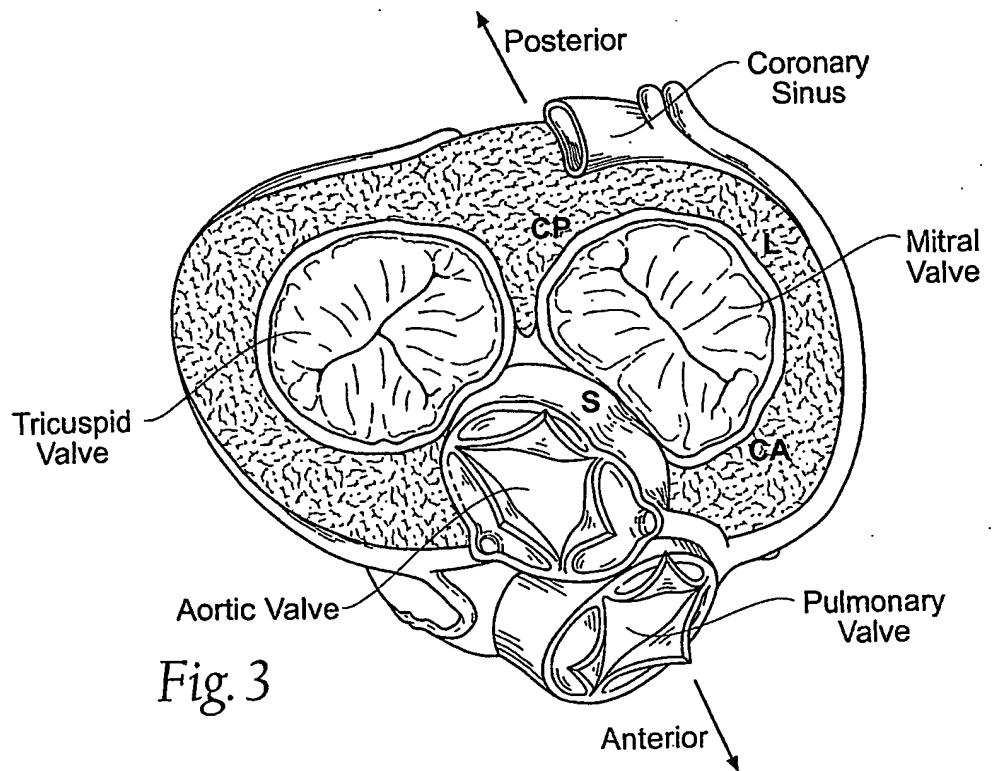
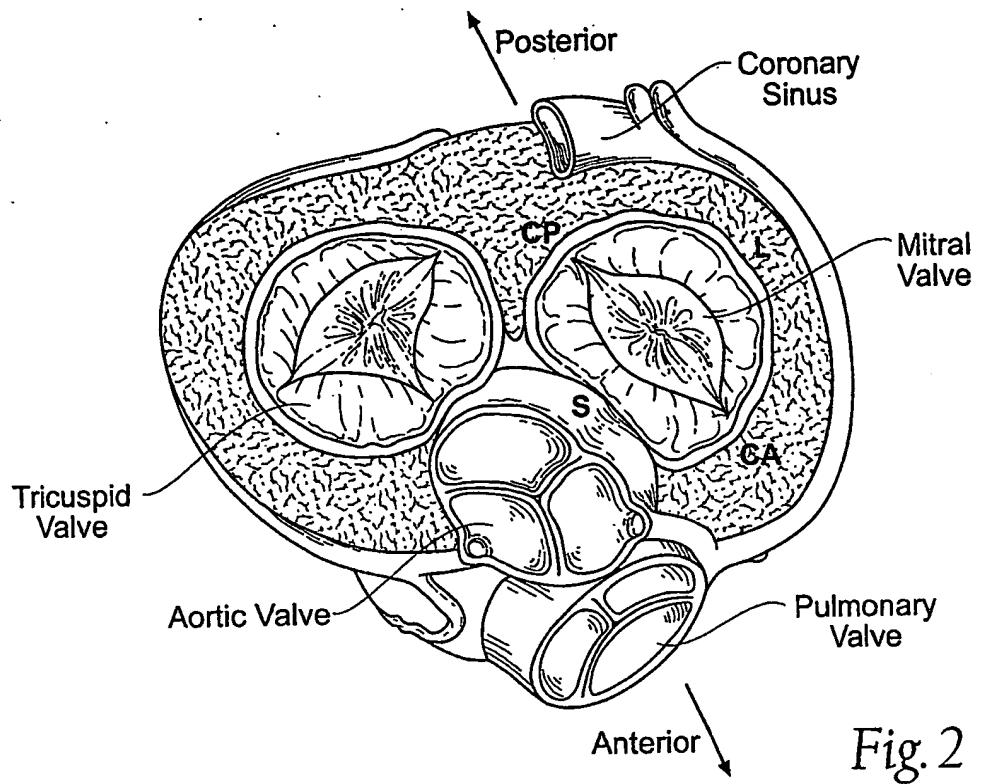


Fig. 1



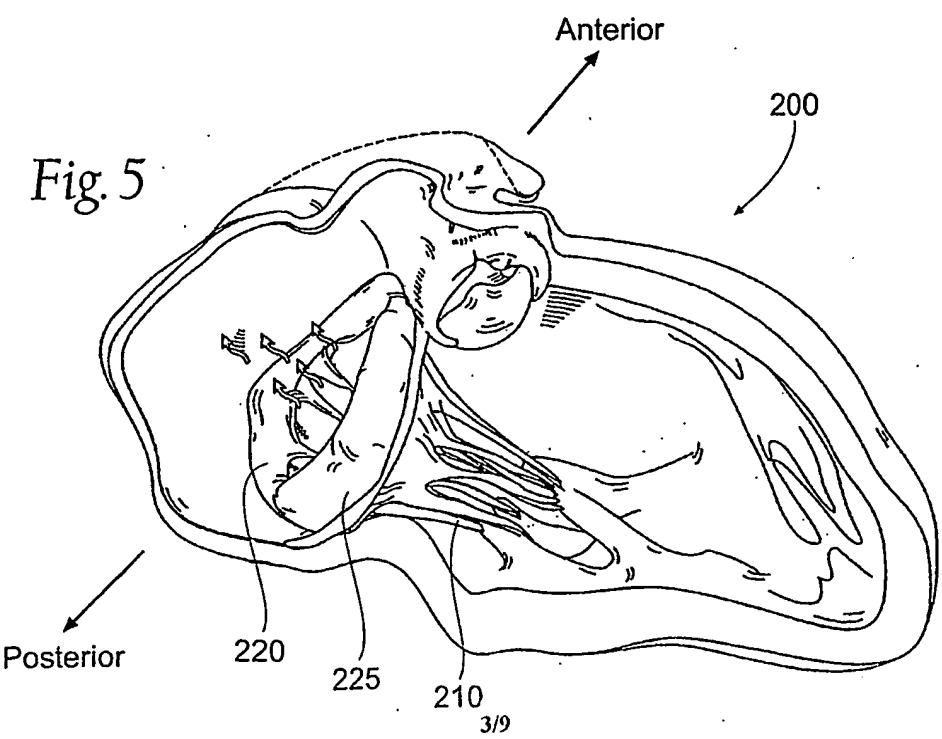
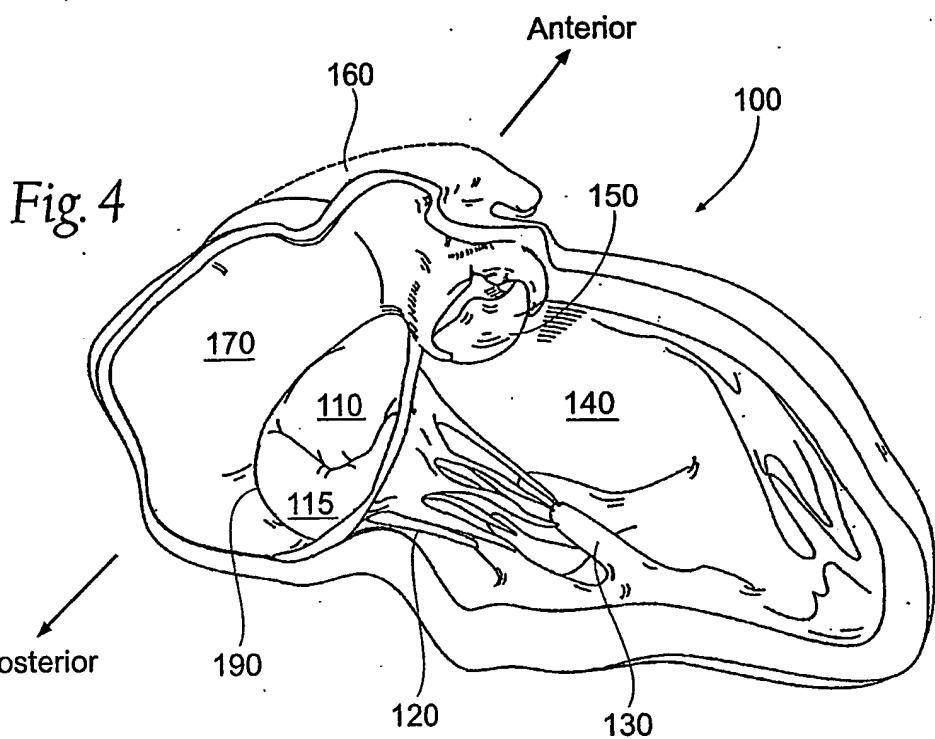


Fig. 6

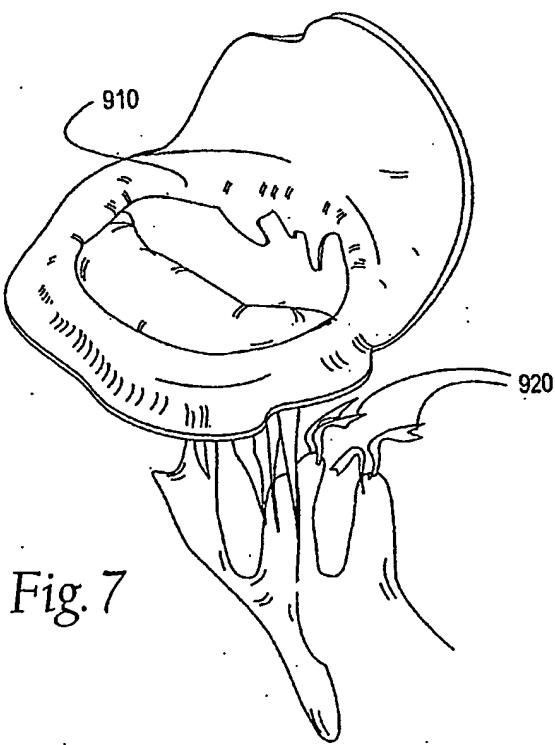
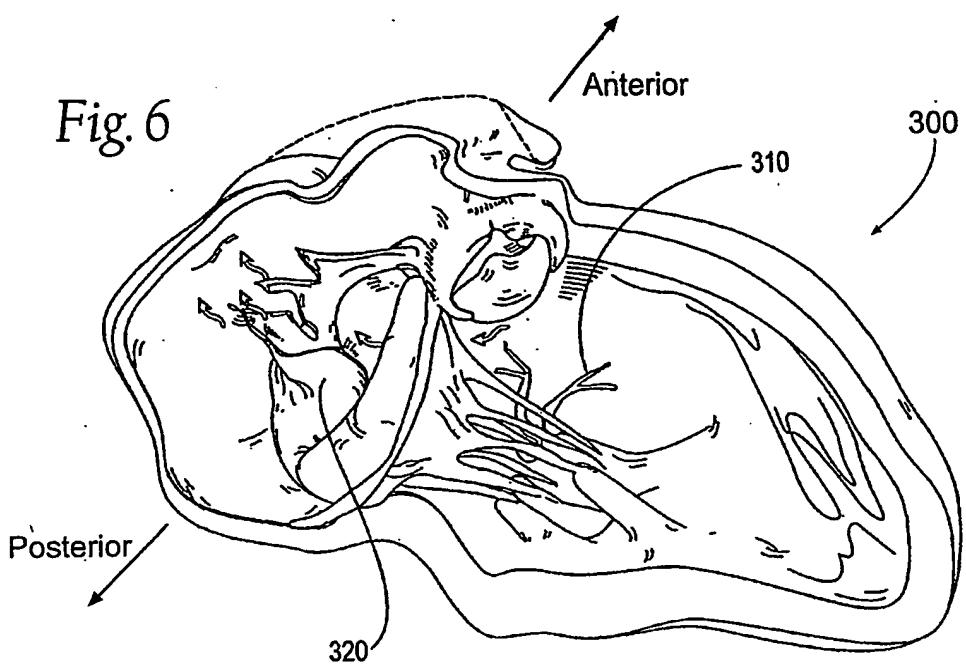
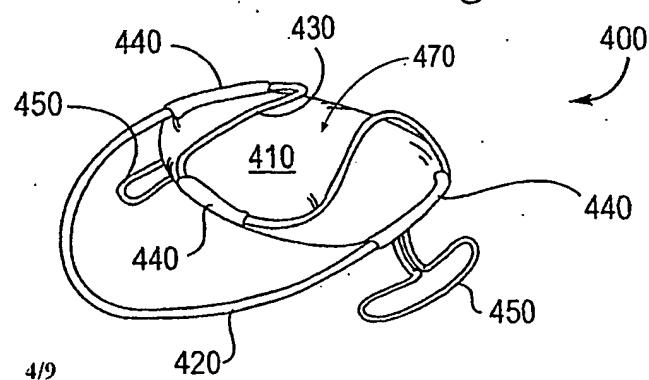


Fig. 7

Fig. 8



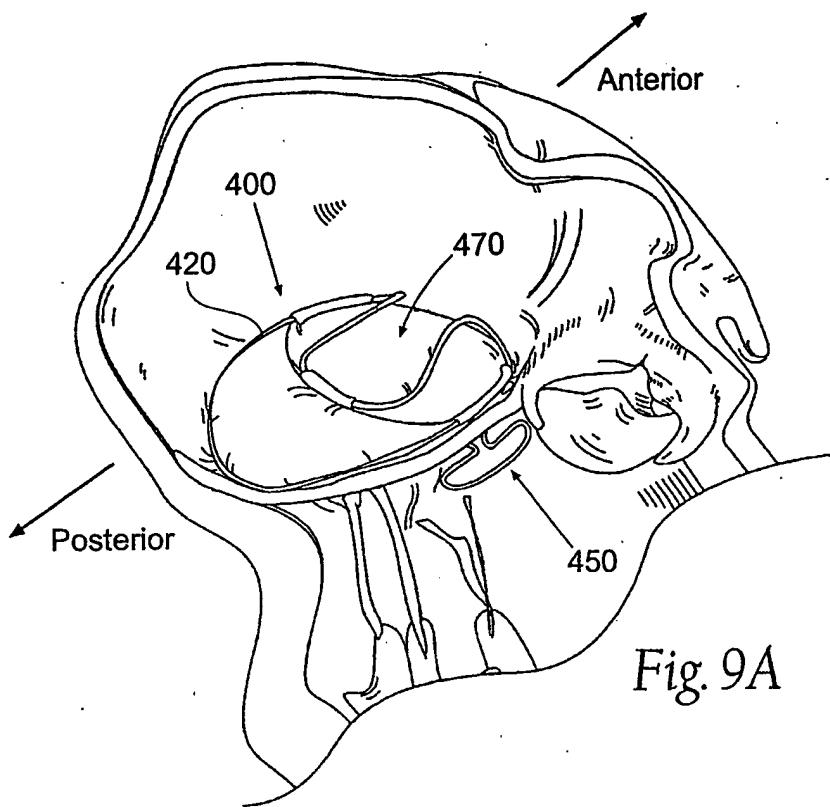


Fig. 9A

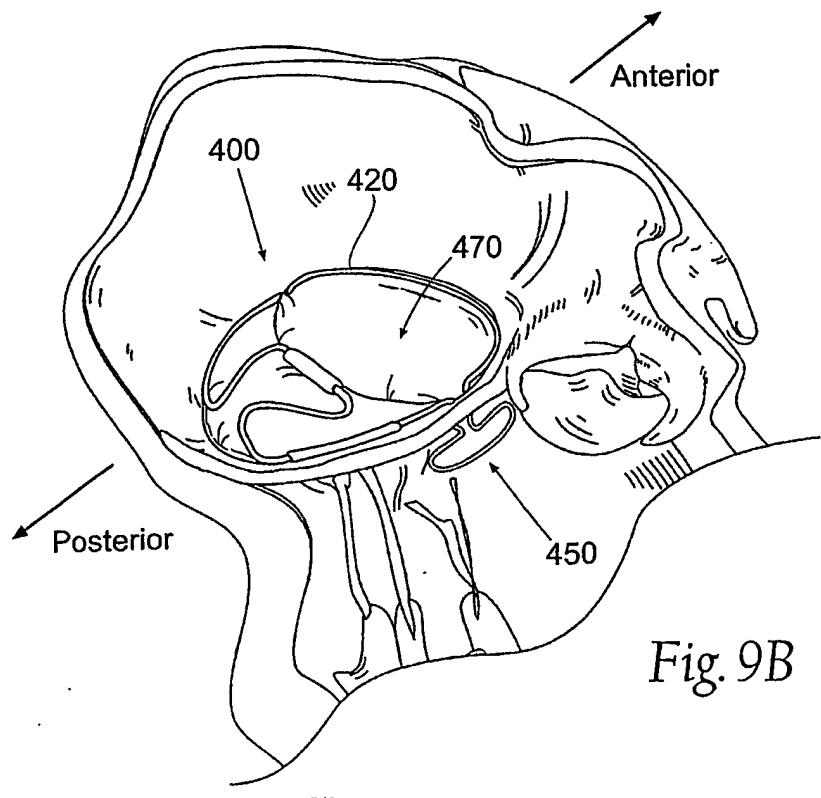


Fig. 9B

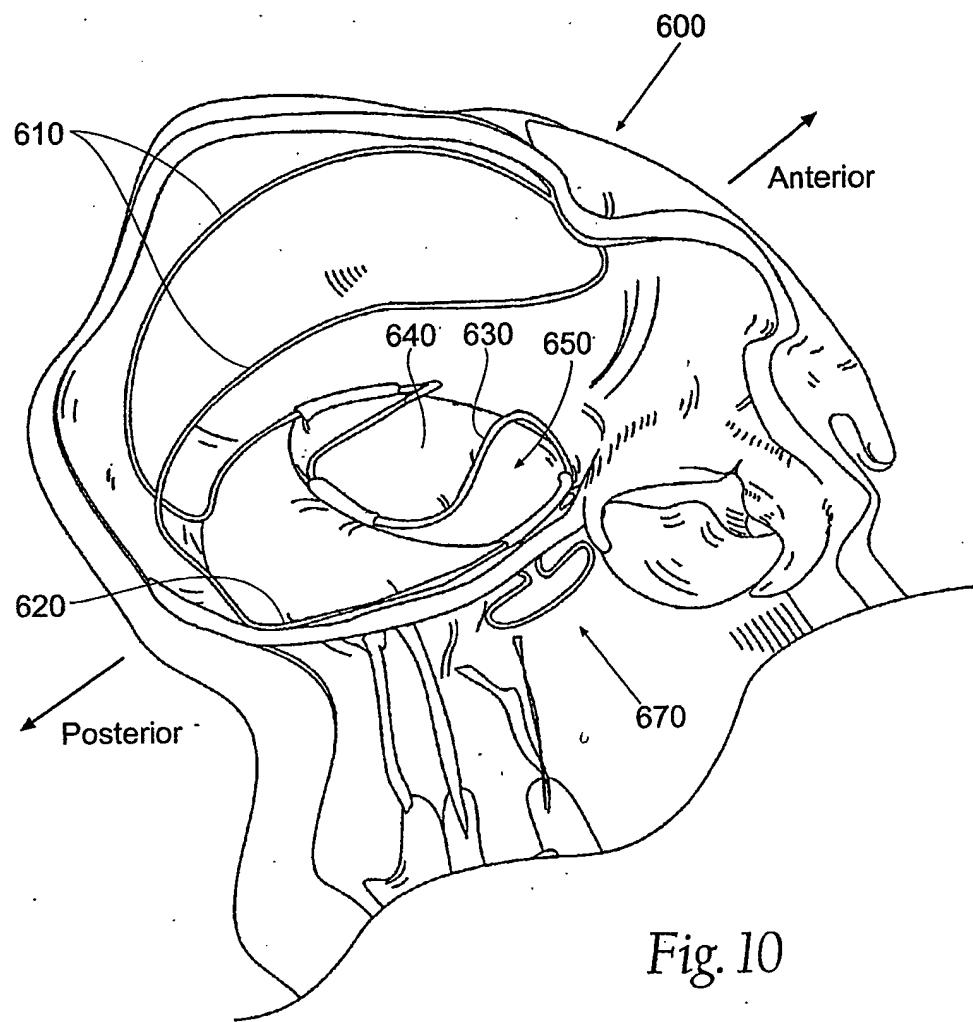


Fig. 10

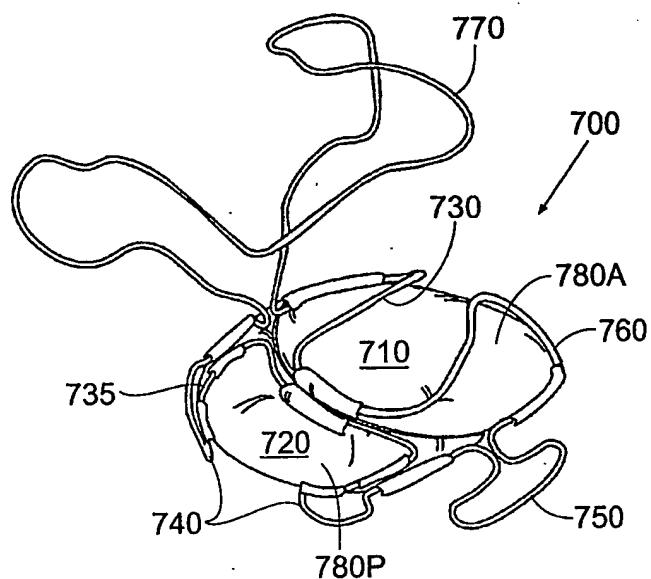


Fig. 11

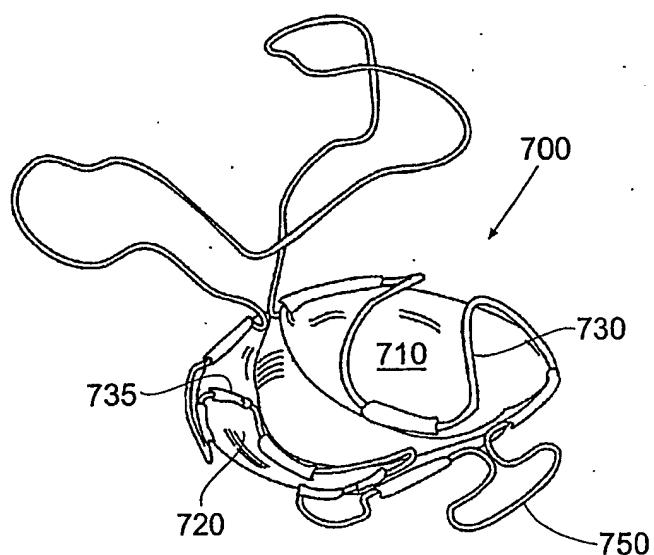


Fig. 12

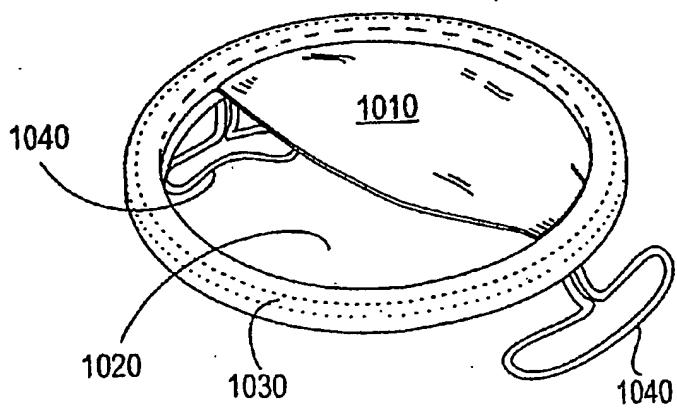


Fig. 13

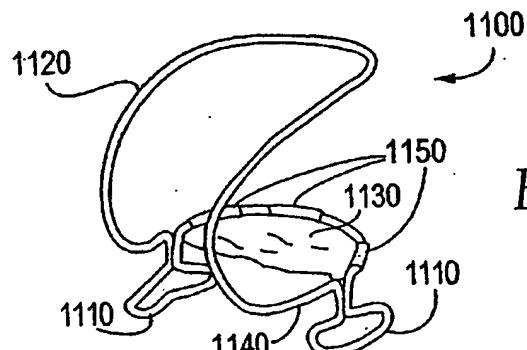


Fig. 14

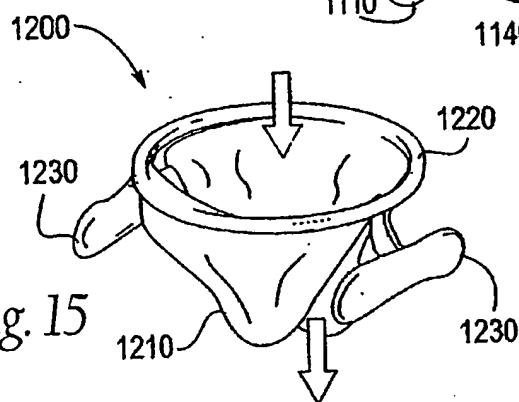


Fig. 15

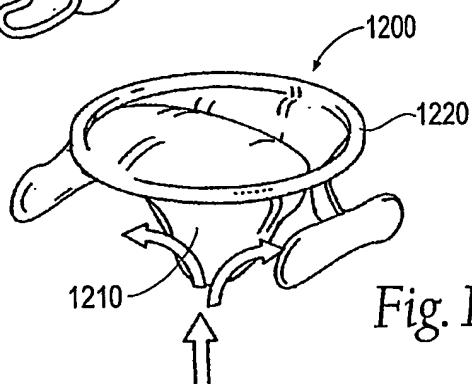


Fig. 16

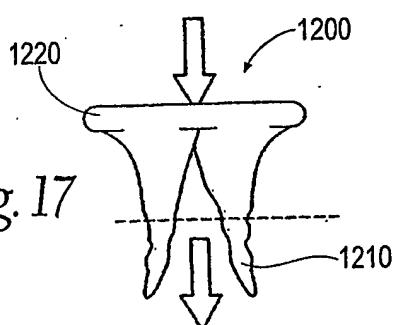


Fig. 17

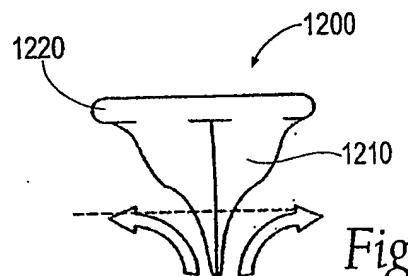


Fig. 18

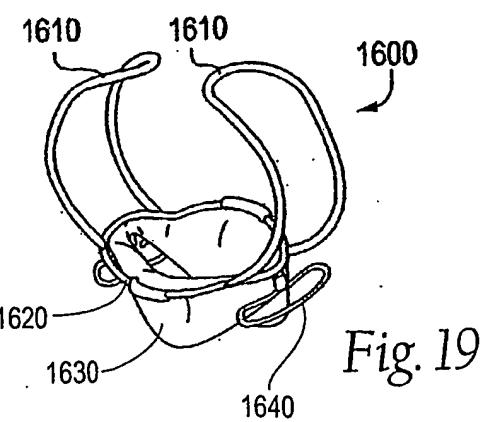


Fig. 19

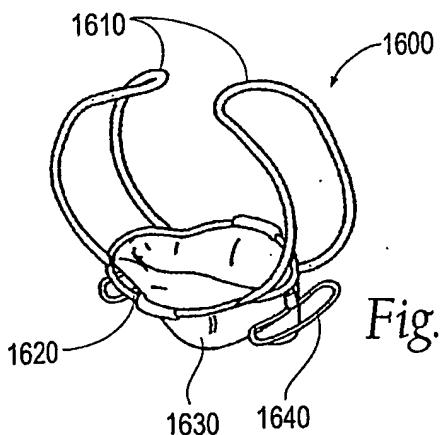


Fig. 20

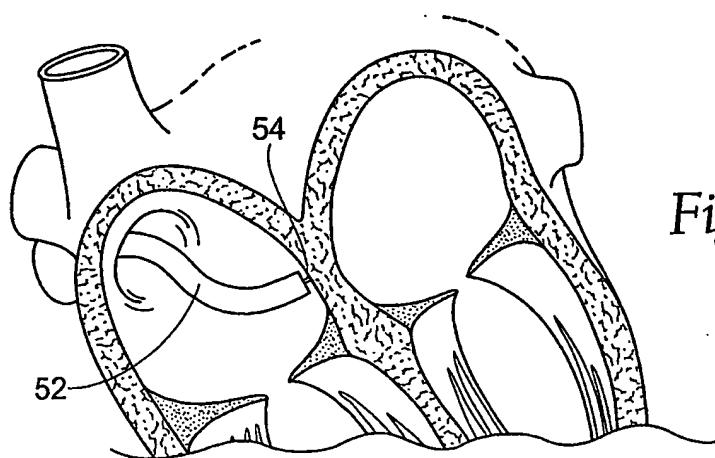


Fig. 21A

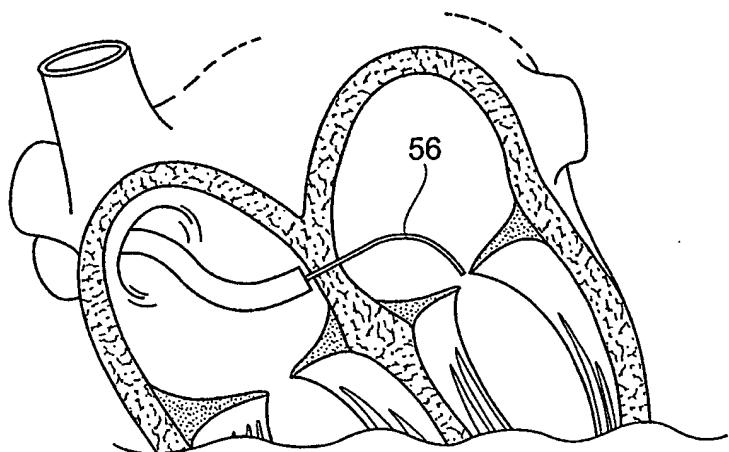


Fig. 21B

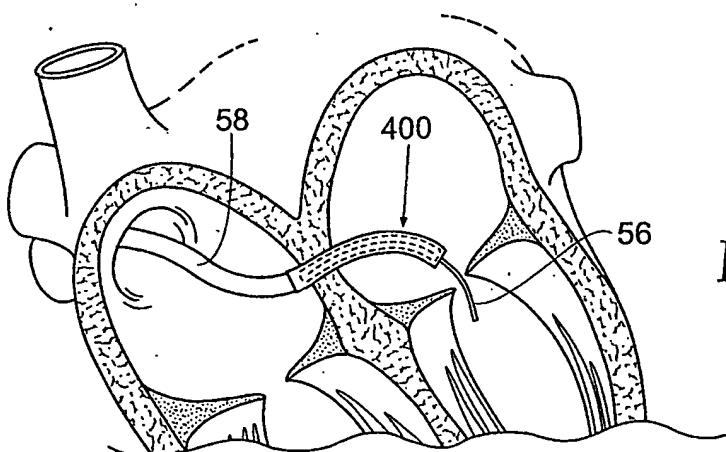


Fig. 21C